

Practitioner's Docket No. MPI00-437P1RM

#### REMARKS

Claims 25, 28, 31, 34, 35, and 40 have been canceled. Claims 26, 27, 29, 30, 32 and 33 have been amended and no new claims have been added. Accordingly, claims 26, 27, 29, 30, 32, 33, 36-39, 41, and 42 will be pending upon entry of the instant amendment. Support for amendments can be found throughout the claims and specification as filed. For example, support may be found in the specification at page, 85, paragraph [0353]; at pages 77-78, paragraph [0320]; at page 85, paragraph [0354]; at page 88, paragraphs [0363] and [0364]; at page 86, paragraph [0355]; and at page 88, paragraph [0366]. No new matter has been added, and Applicants submit that all claims are now in condition for allowance.

Applicants appreciate acknowledgement of priority to applications 60/242,040; 60/242,038; 60/241,992; and 60/242,637.

The specification was objected to for the presence of hyperlink or browser executable code. Applicants point out the preliminary amendment amended the specification to eliminate any http:// reference in order to eliminate browser executable code, according the guidelines of the MPEP. In an effort to advance prosecution, however, the specification has been amended to remove reference to any website address in its entirety. In lieu of the website information, proper reference citation has been included. Applicants submit no new matter has been added by the amendment. For example, the complete information lies in the original specification as filed, at page 18, paragraph 74.

Claims 25, 28, 31, 34, 35, and 40 have been rejected by the Examiner under 35 USC §112, first paragraph, for not enabling a person skilled in the art to make and use the invention in a manner reasonably correlated with the scope of the claims. Applicants have canceled claim 25 (as well as claims 28, 31, 34, 35, and 40), thus rendering the rejection under 35 USC §112 moot. Withdrawal of the rejection is requested.

Claims 26-27, and the dependent Claims 29-30, 32-33, 36-39, and 41-42 have been rejected under 35 USC §112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner has objected to Claims 26-27, line 4, reciting the phrase "amino acid sequence of SEQ ID NO:2 or a full compliment thereof" and rejected the claims as indefinite "because there is no compliment to an amino acid sequence."

Applicants respectfully traverse this rejection, and submit a person of skill in the art would understand the phrase "or a full complement thereof," as stated in the claims refers back to the corresponding nucleotide sequence recited. Applicants acknowledge the fact that there is no complement

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to an amino acid sequence, and submit one skilled in the art would certainly also be aware of this and immediately recognize the "complement thereof" is intended to reference the nucleic acid sequence and not the amino acid sequence. In an effort to address the Examiner's concern and to advance prosecution, Applicants have amended Claim 26 and Claim 27 reciting "or a full complement thereof" to recite "or a full complement of the nucleic acid". It is believed the present amendments are merely duplicative of the recitation prior to amendment, and add no additional meaning or limitations, while addressing the Examiner's concern for any clarification. Further, it is believed the present amendments to claim 26 and claim 27, address the Examiner's objections to dependent claims 28-30, 34-39 and 41-42. Reconsideration and withdrawal of these rejections are respectfully requested.

Claims 28-30, 34-39, and 41-42 have been rejected under 35 USC §112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner objected to the phrase "further comprising vector nucleic acid sequences."

Applicants respectfully traverse this rejection, and submit that Claims 28-30 reciting the objected phrase "further comprising vector nucleic acid sequences," refer to the nucleotide sequences of a vector molecule, and are clear and definite. Applicants further submit one skilled in the art would immediately recognize what the phrase is referencing, and understand the metes and bounds of the claim. In an effort to address the Examiner's objections to the language of the phrase, and to advance prosecution, Applicants have canceled Claim 28 and amended Claims 29-30, to recite, "*A vector comprising the nucleic acid of claim 25.*" Support for these amendments can be found throughout the specification and claims as originally filed, and for example at page 85, paragraph [0353] through page 88, paragraph [362]. It is believed that while the present amendments do not alter the meaning or scope of the claims, and are duplicative of the prior phraseology, the present language addresses the concerns of the Examiner. Reconsideration and withdrawal of the rejections are thus respectfully requested

The examiner has objected to Claims 31-33 for informalities for recitation of "further comprising nucleic acid sequences encoding..."

Applicants submit that inadvertent typographical errors included in Claims 32-33 have been corrected to read, "comprising a nucleic acid *sequence* encoding." Claim 31 has been canceled. Reconsideration and withdrawal of the objections are respectfully requested.

Claims 40-42, regarding a method for producing a polypeptide, have been rejected by the Examiner under 35 USC §112, second paragraph as being incomplete for omitting essential steps. The Examiner has objected to a purported lack of an essential step and suggests inclusion of an additional phrase "into the culture medium and is collected."

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The rejection is traversed. Applicants respectfully submit that the method of production of the polypeptide laid out in Claims 40-42 is complete and does not require an additional step of isolation as the Examiner requires. Applicants point out carrying out the step of the claim as recited would in fact result in the production of the polypeptide as required by the preamble of the claim as recited. However, in the event the Examiner believes the rejection should be maintained, Applicants respectfully request clarification of the requirement.

Claims 25-42 have been rejected under 35 USC §101 by the Examiner because the claimed invention is supported by neither a specific nor a substantial asserted utility. The Examiner's position is that no substantial utility is asserted which is specific to the invention, nor is a relationship to any specific disease taught.

Applicants respectfully traverse the rejection and submit that disclosed utilities for the invention are set forth in the specification which are specific and substantial. For example, at page 21, paragraph 0087, the specification teaches that "the 80090 molecules are predicted to have biological activities as fucosyltransferase family members. Thus, the 80090 molecules can act as novel diagnostic target and therapeutic agents for modulating an immune response, e.g. controlling immunological disorders such as autoimmune disorders, or cell proliferation, e.g. controlling cancer such as gastric tumors". Applicants submit that uses of 80090 molecules in the diagnosis and treatment of immune disorders and cancer constitute specific uses asserted in the specification, as both specific and substantial uses of the provided molecules are taught (e.g., use of the provided 80090 molecules in methods and compositions for diagnosis and/or treatment of disorders of cell proliferation such as immune disorders (e.g., autoimmune disorders), and cancers (e.g., gastric cancer). The uses of the 80090 molecules in diagnosis and treatment of the stated diseases, as diagnostic targets and therapeutic agents of the specific diseases mentioned, constitute a specific, substantial, real world use. Thus, in contrast to the Examiner's assertions, Applicants submit a utility specific and substantial for nucleic acids encoding 80090 has in fact been asserted.

In order to rebut an asserted utility, an Examiner must: *make a prima facie showing of no specific and substantial utility and the Examiner must establish that it is more likely than not that a person skilled in the art would not consider specific and substantial any utility asserted by the applicant for the claimed invention.* See MPEP §2107 II (C) (1). It is not sufficient the Examiner merely indicated disbelief of the asserted utility. The steps that should be taken in order to make an effective rejection should fall under MPEP 2107 (II)(C), where the Examiner is required to make a proper *prima facie* showing of no specific and substantial credible utility. See MPEP 2107(II)(C) (emphasis added):

*(1) Where the asserted utility is not specific or substantial, a prima facie showing must establish that it is more likely than not that a person of ordinary skill in the art would*

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*not consider that any utility asserted by the applicant would be specific and substantial.*

*The prima facie showing must contain the following elements:*

- (i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;*
- (ii) Support for factual findings relied upon in reaching this conclusion; and*
- (iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.*

The Examiner has not made any supported showing to establish more likely than not the utility set forth in the present specification would not be specific, substantial or credible, as sufficient support or factual findings have not been relied upon to make such a showing to rebut Applicants' assertion that the use of the claimed compositions in diagnostics assays and/or identification of therapeutics in disorder of cell proliferation such as inflammation (e.g., autoimmune disorder) or cancers (e.g., gastric cancer) would more likely than not be useful. Rather, the Examiner relies on general arguments to back up the claim that Applicant's original assertion is neither specific nor substantial.

Applicants submit the Examiner has not met the requisite requirement to rebut Applicants asserted utility – no evidence specific to demonstrate Applicants' asserted utility is inoperative, not useful, or contradictory to scientific principles has been presented. Therefore, Applicants respectfully believe the Examiner's imposition of the present rejection is improper in view of the utility guidelines and MPEP §2701, and as such the rejection under 35 USC §101 should be withdrawn.

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### CONCLUSIONS

In view of the amendments and remarks herein, Applicants believe that the objections and rejections presented by the Examiner are now overcome and that this application is in condition for allowance. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

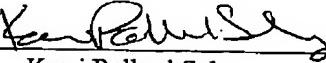
This paper is being filed timely as a request for a two month extension of time is filed concurrently herewith. No additional extensions of time are required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

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MILLENNIUM PHARMACEUTICALS, INC.

By   
Kerri Pollard Schray  
Registration No. 47, 066  
40 Landsdowne Street  
Cambridge, MA 02139  
Telephone - 617-551-3676  
Facsimile - 617-551-8820

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